

1 UNITED STATES DISTRICT COURT
2 FOR THE CENTRAL DISTRICT OF CALIFORNIA
3 EASTERN DIVISION
4 - - - - - X
5 UNITED STATES OF AMERICA, :
6 Plaintiff, :
7 v. : No.
8 CALIFORNIA STEM CELL : 5:18-CV-01005-JBG-KKx
9 TREATMENT CENTER, IND., :
10 Defendants. :
11 - - - - - X
12 Washington, D.C.
13 Friday, June 7, 2019
14 Deposition of LOLA M. REID, Ph.D., a
15 witness herein, called for examination by counsel for
16 Plaintiff in the above-entitled matter, pursuant to
17 notice, the witness being duly sworn by MARY GRACE
18 CASTLEBERRY, a Notary Public in and for the District
19 of Columbia, taken at the offices of United States
20 Department of Justice, 450 Fifth Street, N.W.,
21 Washington, D.C., at 10:02 a.m., Friday, June 7,
22 2019, and the proceedings being taken down by

1 Stenotype by MARY GRACE CASTLEBERRY, RPR, and
2 transcribed under her direction.

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1 APPEARANCES:

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3 On behalf of the Plaintiff:

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5 United States Department of Justice

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9 and

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11 Associate Chief Counsel

12 MICHAEL SHANE, ESQ.

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20 (240) 402-6165

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1 APPEARANCES (Continued):

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3 On behalf of the Defendants:

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6 600 Massachusetts Avenue, N.W.

7 Washington, D.C. 20001

8 (202) 344-4398

9

10 ALSO PRESENT:

11 KRISTEN CANALES, Intern

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1 it.

2 Q. I'm just trying to figure out, are you
3 referring to the same thing you told us at the
4 beginning, which is last night you downloaded some
5 information from the FDA's website for the first
6 time, correct?

7 A. Correct. That is correct.

8 Q. And it's your understanding that
9 definitions that speak to which products would
10 require an IND or an NDA, that that can be found in
11 some of the materials you downloaded for the first
12 time last night?

13 A. Correct.

14 Q. And had you consulted any rules or laws
15 addressing this point at any time before last night?

16 A. Yes. I talked with Steven Rhodes, who is
17 a regulatory agent actually working at the FDA, and
18 this is like six months ago, as we're beginning this
19 whole process of transitioning to what we hope will
20 be clinical trials in the coming year. And he was
21 explaining to me about that we're going to have to go
22 through a more complicated route of getting approval

1 than other people who are doing cell therapies where
2 there are simpler protocols because we're making
3 these grafts. And so he -- I mean, I talked with him
4 on a couple of occasions, but it had nothing to do
5 with what we're talking about here. It had to do
6 with what we're hoping to do in a year or two.

7 Q. Well, let's turn now to what we're talking
8 about here, which is adipose-derived stromal vascular
9 fraction. Why do you believe that no FDA approvals
10 are necessary for stromal vascular fraction?

11 MS. GARDNER: Objection. It
12 mischaracterizes the report.

13 BY MS. SANDERS:

14 Q. Let me ask this. You spoke about
15 composite articles or products that you believe need
16 to go through the IND or NDA process.

17 A. Correct.

18 Q. And you contrasted that with the kinds of
19 stromal vascular fraction products that are at issue
20 in this case. And I'm simply trying to understand
21 what the basis for your distinction is. Why do you
22 believe that no FDA approval is needed for the

1 stromal vascular fraction articles?

2 MS. GARDNER: Objection. Vague. Are you
3 talking about the defendants' article?

4 MS. SANDERS: I'm first talking in
5 general.

6 BY MS. SANDERS:

7 Q. I'm asking is your --

8 MS. GARDNER: Objection. Mischaracterizes
9 her testimony.

10 BY MS. SANDERS:

11 Q. Well, let me --

12 A. I can actually answer it pretty easily,
13 okay? I think there are times when the FDA will have
14 to be involved, but I think at its simplest, taking
15 cells out, if you use really purified conditions like
16 purified collagenase, you can isolate cells that are
17 essentially like they are in vivo and giving them
18 back in another site is a perfectly safe procedure.
19 It's like taking blood samples from a patient and
20 giving them back to another patient.

21 But I distinguish that from doing things
22 like culturing them or adding another product to them

1 like a virus. There I don't agree. I think there
2 you really have to do your homework and know whether
3 they're safe to give. But just to take them out and
4 re-isolate cells all the time from tissues, from
5 solid tissues and with the most minimal procedures
6 that we use, you should be able to give those cells
7 back because you haven't done anything to harm them.

8 Obviously you have to be careful what you
9 use, what enzymes you use. They have to be very
10 pure. And you can't use certain ones that are known
11 to harm the antigenicity of the cells. But to take
12 the cells out, do a very simple procedure,
13 immunoselect them by magnet beads or there are some
14 other panning methods that can be used for it. Those
15 are very simple and then those cells can be given
16 back. And you've done nothing to harm those cells,
17 all right?

18 And the fortunate thing is that the
19 stromal vascular fraction contains cells that have
20 paracrine signals that indeed can suppress chronic
21 inflammation. And I think it's going to be wonderful
22 for people, for at least certain forms of disease

1 states, that those should be allowed.

2 Anything that starts with that, but then
3 does some modifications, I think you've got to have
4 to worry about what you're going to be doing. But
5 just the simple thing of getting out a cell,
6 isolating it and giving it back to that patient
7 should be perfectly safe.

8 Q. If I heard you correctly, adding a vaccine
9 to a collection of cells is something that you think
10 does require FDA approval, correct?

11 A. It is. I do.

12 Q. And you would also agree that expanding
13 stromal vascular fraction cells is also something
14 that requires FDA approval, correct?

15 MS. GARDNER: Objection. Calls for a
16 legal conclusion.

17 MS. SANDERS: I'm asking her for her
18 opinion. I'm not asking her to give a legal opinion.

19 BY MS. SANDERS:

20 Q. I just want your scientific, informed
21 judgment.

22 A. I'm an expert in the whole ex vivo

1 maintenance of cells and so there it would be a
2 qualified answer because depending on exactly how you
3 did it, you could alter the cells in a way that would
4 not be good. But you can maintain them ex vivo in
5 certain forms where it's safe for a narrow window of
6 time. But the longer you have them ex vivo, they are
7 changing. And then increasingly you're getting to
8 the point where you're going to have to then really
9 do your homework, all right?

10 So the ones that I think -- the simplest
11 are you take them out, you fish them out with
12 extremely pure enzymes and you have a subpopulation
13 that you're choosing, those should be able to be
14 given back, all right? Without problems.

15 Q. So let me address the two points you made.
16 With respect to cells that are expanded in culture,
17 for clarity, you think there are instances where FDA
18 approval should be obtained, correct?

19 A. For some of them.

20 Q. But for some you would say FDA approval is
21 not required, correct?

22 A. Yes. It's --

1 Q. Now, for --

2 A. Yes.

3 Q. -- the stromal vascular fraction article
4 that defendants use in this case, it's your opinion
5 that FDA approval is not required at any time,
6 correct?

7 MS. GARDNER: Objection. Vague.

8 THE WITNESS: No. I've already told you I
9 don't agree with that. I said that to fish out the
10 cells, to use a super pure collagenase or one of the
11 Liberase versions which are enzyme mixes that are
12 very pure, those cells should be able to be given
13 back.

14 So if it is autologous cell therapy,
15 you're giving them back to the same patient. You're
16 not doing expansion -- even expansion theoretically
17 could indeed be perfectly safe, but there I'm
18 hesitant to give carte blanche on that because it
19 depends on what you do. But just to get them out, to
20 fish them back and then to give them back, I think,
21 is perfectly safe.

22 BY MS. SANDERS:

1 Q. Isn't it true, Dr. Reid, that scientists,
2 researchers, doctors in fields have differing views
3 on the things that you've been discussing in your
4 most recent answer?

5 Or let me say it this way. You think that
6 stromal vascular fraction cells that should be -- let
7 me rephrase.

8 If I understood you correctly, the
9 combination of stromal vascular fraction cells with a
10 vaccine is something that should require FDA
11 approval. Isn't it true that there are scientists
12 and perhaps other researchers who may share a
13 different view on that question?

14 A. I think -- I'm sure they do. But there is
15 one where -- I have enough knowledge about the
16 viruses -- and when you put viruses in there, then
17 there are many things that can happen. So I would
18 be --

19 Q. Fair enough.

20 A. -- nervous about doing that.

21 Q. Sure. So where would we look to resolve
22 the question? Someone says FDA approval is required.

1 Someone else doesn't want to seek FDA approval. Are
2 you aware of a source that answers that question?

3 A. Actually, the patients answer it. Gosh,
4 think about all the decades we've done blood -- taken
5 blood samples and we've fractionated them and you put
6 the patients through dialysis and you're
7 fractionating the cells in one way or another and
8 you're giving them back.

9 So how do you know -- at what point do you
10 say, okay, there's going to have to be more work
11 done. If you start getting a percentage of patients
12 who are having some type of aberration because of
13 what you're doing, that says, okay, we've got to back
14 up here and figure out what's going on. But when
15 they're giving T cells or B cells or platelets or
16 erythrocytes, to my knowledge, they don't require FDA
17 approval for that.

18 Q. And what is your knowledge based on?

19 A. This is just by associates who are
20 hematologists.

21 Q. So something that someone has told you who
22 has studied hematology, that's the source of your

1 knowledge?

2 A. Yes.

3 Q. And it's your opinion that experimental
4 treatments should be permitted and to the extent that
5 there are problems, that will be cleaned up on the
6 back end; is that --

7 A. No, not at all. No. But right now there
8 are a number of types of procedures that are done
9 that now are not -- to my knowledge are not regulated
10 by the FDA and most of them have to do with
11 hemopoietic cells. But hemopoietic cells are ones
12 that have evolved over the millennia to float. So
13 they have cell binding domains, they have isoforms in
14 which they can switch between having cell binding
15 domains and not having cell binding domains.

16 And the fact that there are phases where
17 they don't have cell binding domains means that
18 fractionation of them is much, much easier. And so
19 there are ways by size, by sieving, by
20 immunoselection with antibodies that you can fish out
21 a particular population and then they give them back
22 to the patient in one form or another.

1 Q. I see. Are you familiar with the Federal
2 Food, Drug and Cosmetic Act?

3 A. I know of it. I have no knowledge --
4 detailed knowledge of it at all.

5 Q. Are you familiar with the Public Health
6 Service Act?

7 A. I know of it, but I don't know the
8 details.

9 Q. Are you familiar with various regulations
10 that govern drugs in Title 21 of the Code of Federal
11 Regulations?

12 A. I have no idea.

13 Q. What's a drug?

14 A. Well, a drug is a chemical that can be
15 delivered to a patient by some route and has an
16 alteration in the biological properties and the
17 phenotypic traits of the cells.

18 Q. Are you aware, Dr. Reid, that there is a
19 legal definition of a drug?

20 A. I'm sure there is, but I don't know what
21 it is.

22 Q. Do you know where you would look to find

1 CERTIFICATE OF REPORTER

2 UNITED STATES OF AMERICA) ss.:

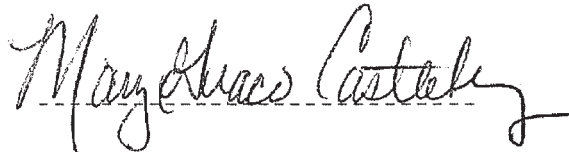
3 DISTRICT OF COLUMBIA)

4 I, MARY GRACE CASTLEBERRY, RPR, the officer before whom
5 the foregoing proceedings were taken, do hereby
6 certify that the foregoing transcript is a true and
7 correct record of the proceedings; that said
8 proceedings were taken by me stenographically to the
9 best of my ability and thereafter reduced to
10 typewriting under my supervision; and that I am
11 neither counsel for, related to, nor employed by any
12 of the parties to this case and have no interest,
13 financial or otherwise, in its outcome.

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Notary Public in and for

18

The District of Columbia

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20 My commission expires: July 14, 2021

